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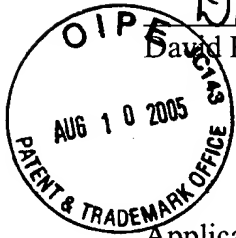
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313 on the date shown below:

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322  
Docket No. UF-T278  
Patent No. 6,796,305 B1

August 8, 2005

David R. Saliwanchik

David R. Saliwanchik, Patent Attorney



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Banner *et al.*  
Issued : September 28, 2004  
Patent No. : 6,796,305  
For : Ventilator Monitor System and Method of Using Same

Mail Stop Certificate of Corrections Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Certificate  
AUG 12 2005  
of Correction

REQUEST FOR CERTIFICATE OF CORRECTION  
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:

Column 3, line 62:

modem

Application Reads:

Page 6, line 1:

modern

**Patent Reads:**Column 4, line 8:

modem

Column 6, line 3:

(SIMY);

Column 6, line 60:

at least. one

Column 7, line 40:

a-plurality

Column 8, line 18:

attache dot

Column 8, line 21:

to, the arm

Column 8, line 25:

data maybe

Column 8, line 25:

derived form

Column 10, line 30:

the sun of

Column 19, line 2, (Claim 1):

the signals;

**Application Reads:**Page 6, line 15:

modern

Page 10, line 11:

(SIMV);

Page 11, line 24:

at least one

Page 12, line 29:

a plurality

Page 13, line 33:

attached to

Page 14, line 1:

to the arm

Page 14, lines 3-4:

data may be

Page 14, line 4:

derived from

Page 17, line 25:

the sum of

Page 2 of Response dated April 21, 2004,  
Claim 39, line 10:

the output signals;

**Patent Reads:**Column 19, line 17, (Claim 2):

sorting controls,

Column 20, line 30, (Claim 10):

wherein comprising:

**Application Reads:**Page 2 of Response dated April 21, 2004,  
Claim 40, line 4:

setting controls,

Page 4 of Response dated April 21, 2004,  
Claim 48, line 1:

further comprising:

True and correct copies of the application as filed and the Response dated April 21, 2004 which support the Applicants' assertion of the error on the part of the Patent Office accompany this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,



David R. Saliwanchik

Patent Attorney

Registration No. 31,794

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

DRS/hey

Attachments: Certificate of Correction in duplicate;  
Copy of Response dated April 21, 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

Page 1 of 2

PATENT NO. : 6,796,305  $\beta$  1  
DATED : September 28, 2004  
INVENTORS : Banner *et al.*

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3,  
Line 62, "modem" should read – modern –.

Column 4,  
Line 8, "modem" should read – modern –.

Column 6,  
Line 3, "(SIMY);" should read – (SIMV); –.

Column 6,  
Line 60, "least. one" should read – least one –.

Column 7,  
Line 40, "a-plurality" should read – a plurality –.

Column 8,  
Line 18, "attache dot" should read – attached to –.

MAILING ADDRESS OF SENDER:  
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PATENT NO. 6,796,305


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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

Page 2 of 2

PATENT NO. : 6,796,305   
DATED : September 28, 2004  
INVENTORS : Banner *et al.*

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Column 8,

Line 25, "derived form" should read – derived from –.

Column 10,

Line 30, "sun of" should read – sum of –.

Column 19,

Line 2, (Claim 1), "the signals;" should read – the output signals; –.

Column 19,

Line 17, (Claim 2), "sorting controls," should read – setting controls, –.

Column 20,

Line 30, (Claim 10), "wherein comprising:" should read – further comprising: –.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

Page 1 of 2

PATENT NO. : 6,796,305 *131*  
DATED : September 28, 2004  
INVENTORS : Banner *et al.*

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Column 7,

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PATENT NO. 6,796,305

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

Page 2 of 2

PATENT NO. : 6,796,305 *B1*  
DATED : September 28, 2004  
INVENTORS : Banner *et al.*

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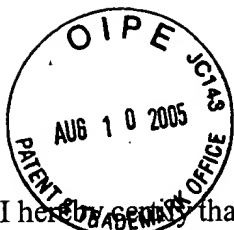
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PATENT NO. 6,796,305

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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date shown below:

RESPONSE UNDER 37 CFR §1.116  
Examining Group 3761  
Patent Application  
Docket No. UF-T278  
Serial No. 09/608,200

April 21, 2004  
David Saliwanchik  
David R. Saliwanchik, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Mital B. Patel  
Art Unit : 3761  
Applicants : Michael Banner, Neil R. Euliano, Jose Principe, and Paul Blanch  
Serial No. : 09/608,200  
Filed : June 30, 2000  
For : Ventilator Monitor System and Method of Using Same

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RESPONSE UNDER 37 CFR §1.116

A Petition and Fee for a three-month Extension of Time through and including April 21, 2004 accompanies this Amendment.

In response to the Office Action dated October 21, 2003, please amend the above-referenced patent application to read as follows:

**Amendments to the Claims** are reflected in the listing of claims beginning on page 2 of this paper.

**Remarks/Arguments** follow the amendment sections of this paper.



In the Claims

This listing of claims will replace all prior versions and listings of claims in this application.

39 (currently amended) A method for monitoring ventilation support for a patient having an airway, wherein said method comprises:

(1) ~~providing~~ utilizing a monitoring system comprising:

(a) a plurality of measuring sensors ~~adapted to~~ that monitor the patient, or ~~to~~ that monitor a breathing circuit coupled to the airway of the patient, each measuring sensor generating an output signal, and

(b) an intelligence system ~~adapted to receive the~~ that receives at least one of the output signals, wherein the intelligence system evaluates at least one output signal to determine the appropriateness of ventilation for the patient;

(2) receiving into the intelligence system at least one of the output signals;

(3) implementing the intelligence system, without clinician input, to evaluate the at least one output signal to determine the appropriateness of ventilation for the patient; and

(4) recommending, without clinician input, a setting for at least one of the plurality of ventilator setting controls based on the evaluation of the at least one output signal by the intelligence system, wherein said setting is appropriate for the patient at that particular time.

40 (previously presented). The method of claim 39, further comprising providing a ventilator adapted to supply a gas to a patient via a breathing circuit in fluid communication with at least one lung of the patient, wherein the ventilator is operatively connected to the intelligence system, and wherein the ventilator includes a plurality of ventilator setting controls, wherein each ventilator setting control controls a parameter relating to the supply of gas from the ventilator to the patient.

41 (previously presented). The method of claim 40, further comprising:

causing the ventilator to generate a ventilator parameter signal indicative of a parameter related to the supply of gas from the ventilator to the patient; and

providing the ventilator parameter signal to the intelligence system, wherein the intelligence system evaluates the at least one output signal and the ventilator parameter signal to determine the appropriateness of ventilation.

42 (previously presented). The method of claim 40, further comprising adjusting at least one of the plurality of ventilator setting controls based on the setting determined in the recommending step.

43 (previously presented). The method of claim 39, wherein said output signals are selected from the group consisting of: an exhaled carbon dioxide signal indicative of the exhaled carbon dioxide ( $\text{ExCO}_2$ ) level of the exhaled gas expired by the patient within the breathing circuit; a flow rate signal indicative of the flow rate ( $V$ ) of the inhaled/exhaled gas expired by the patient within the breathing circuit; a pulse oximeter hemoglobin oxygen saturation ( $\text{SpO}_2$ ) signal indicative of the oxygen saturation level of the patient; a pressure ( $P$ ) signal indicative of the pressure of the breathing gas within the breathing circuit; a blood pressure ( $\text{BP}$ ) signal indicative of the blood pressure of the patient; and a temperature ( $T$ ) signal indicative of the core body temperature of the patient.

44 (previously presented). The method of claim 43, wherein the output signals also include at least one of the group consisting of: an arterial blood gas  $\text{PaO}_2$  signal; an arterial blood gas  $\text{PaCO}_2$  signal; and an arterial blood gas pH signal.

45 (previously presented). The method of claim 39, wherein the ventilator parameter signals include at least one of the group consisting of: a minute ventilation ( $V_E$ ) signal; a ventilator breathing frequency of ( $f$ ) signal; a tidal volume ( $V_T$ ) signal; a breathing gas flow rate ( $V$ ) signal; a pressure limit signal; a work of breathing ( $\text{WOB}$ ) signal; a pressure support ventilation ( $\text{PSV}$ ) signal; a positive end expiratory pressure ( $\text{PEEP}$ ) signal; a continuous positive airway pressure ( $\text{CPAP}$ ) signal; and a fractional inhaled oxygen concentration ( $\text{FIO}_2$ ) signal.

46 (previously presented). The method of claim 39, further comprising displaying the recommended settings of the ventilator setting controls.

47 (previously presented). The method of claim 39, wherein the intelligence system comprises a neural network, and wherein recommending the settings of the ventilator setting controls of the ventilator comprises applying at least a portion of the output signals and the ventilator parameter signals to the neural network of the intelligence system to determine the recommended settings of the ventilator setting controls.

48 (previously presented). The method of claim 39, further comprising:  
selecting output signals for display; and  
displaying the selected output signals in real time.

49 (previously presented). The method of claim 39, further comprising displaying at least one of the recommended ventilator setting control settings.

50 (previously presented). The method of claim 39, wherein the intelligence system is programmed with a set of decision rules.

51 – 62 (cancel).

Remarks

Claims 39-62 were pending in the subject application. By this Amendment, claim 39 has been amended and claims 51-62 have been cancelled. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 39-50 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

The applicants wish to thank Examiner Patel for the courtesy of the examiner interview conducted with the undersigned on April 20, 2004. The remarks and amendments set forth herein are consistent with the substance of that interview and are believed to address the outstanding issues as discussed during the examiner interview.

The amendments to the claims set forth herein have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 39-62 have been rejected under 35 U.S.C. §102(b) as being anticipated by Biondi *et al.* (U.S. Patent No. 6,158,432). The applicants respectfully traverse this grounds of rejection because the Biondi *et al.* reference does not teach or suggest the applicants' unique method for ventilation monitoring and control. Specifically, Biondi *et al.* does not disclose a system that recommends, without clinician input, a ventilator control setting for a particular patient at that particular time based on the evaluation by an intelligence system of at least one output signal.

The Biondi *et al.* system requires the clinician to select specific ventilator control settings. The Biondi *et al.* system then monitors the performance of the system and, based on simulator algorithms, adjusts the mechanics of the system to effect the directions that were selected by the clinician. The Biondi *et al.* system does not, and cannot, recommend appropriate settings without clinician input to best facilitate patient care. Rather, the Biondi *et al.* system simply tries to carry out the operator's instructions. It is important to recognize that, when the current applicants refer to

“ventilation control settings” they are referring to the settings that, when using the Biondi *et al.* system, must be entered by a clinician.

Please note the following passage in the Biondi *et al.* patent.

One feature of the ventilator control system 10 is that it can be configured to provide an assisted phase of a breath to the patient 20. As noted previously, the accumulated volume of gas inhaled by the patient as a result of his spontaneous respiratory muscle activity can be monitored. To accomplish this, the sensor monitoring system 19 measures the flow of gas inhaled by the patient 20 at the beginning of the inspiration phase of the breath and integrates the flow to provide the measured volume. The embedded controller 14 compares the measured volume to a trigger volume set by the clinician 16, and adjusts the plurality of controls within the pneumatic system 41 when the measured accumulated volume exceeds the trigger volume to provide an assisted phase of a breath. The embedded controller 14 also may adjust the trigger volume dynamically according to measured patient flow and pressure signals indicating the phase of the respiratory cycle. In particular, the embedded controller 14 may increase the trigger volume set by the clinician 16 during periods of the breath where increasing the pressure at the airway of the patient 20 may be induced by changes in the pneumatic system 41, and not by spontaneous efforts of the patient.

The applicants respectfully submit that the cited passage illustrates important distinctions between the applicants’ invention and the Biondi *et al.* system. Please note, for example, the reference to input provided by the clinician (fourth sentence). The simulator disclosed by Biondi *et al.* applies predetermined data structures with predetermined computational instructions to monitor patient ventilation (see for example, col. 13, line 57 through col. 14, line 62). This is in contrast of the current invention.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH*,

*supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2nd Cir. 1942).

The current applicants respectfully submit that Biondi *et al.* do not disclose the currently-claimed method wherein, without clinician input, an intelligence system evaluates output signals and ventilator parameter signals to recommend ventilator control settings. Because Biondi *et al.* do not disclose such a system, the applicants' claims cannot be said to be anticipated by Biondi *et al.*

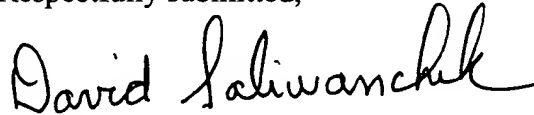
The distinctions between the current invention and the Biondi *et al.* system are not trivial. In fact, it is precisely the differences between the current invention and Biondi *et al.* that make the current invention particularly advantageous. The Biondi *et al.* system only uses rigid algorithms to try to control the ventilator in order to effect settings entered by the operator. Thus, the care of the patient still depends entirely on judgments made by the operator. In contrast, the subject invention provides a system whereby a multiplicity of variables can be monitored in order to assess the need of a particular patient. These variables, which can include various measures of the patient's physiological response to the ventilator can then be used to achieve the appropriate therapeutic goal. By carefully monitoring the patient in this way, it is now possible to improve and expedite recovery. This is, of course, a tremendous benefit to the patient, the caregiver and the hospital. Such an advantageous method is neither disclosed nor suggested by Biondi *et al.* Accordingly, the applicants respectfully request reconsideration and withdrawal of the prior art rejection based on Biondi *et al.*

In view of the foregoing remarks and amendment, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



David R. Saliwanchik

Patent Attorney

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Gainesville, FL 32606-6669

DRS/la

5  
**VENTILATOR MONITOR SYSTEM AND METHOD OF USING SAME**

10  
**BACKGROUND OF THE INVENTION**

**Field of the Invention:**

15 The present invention relates to the respiratory care of a patient and, more particularly, to a ventilator monitor system that receives a plurality of ventilator support signals indicative of the sufficiency of ventilation support received by the patient, receives at least one ventilator signal indicative of the level settings of the ventilator setting controls of the ventilator, and determines the desired level settings of the ventilator setting controls of the ventilator to provide the appropriate quality and quantity of ventilation support to the patient.

20 **Background:**

25 Mechanical ventilatory support is widely accepted as an effective form of  
therapy and means for treating patients with respiratory failure. Ventilation is the process of delivering oxygen to and washing carbon dioxide from the alveoli in the lungs. When receiving ventilatory support, the patient becomes part of a complex interactive system which is expected to provide adequate ventilation and promote gas exchange to aid in the stabilization and recovery of the patient. Clinical treatment of a ventilated patient often calls for monitoring a patient's breathing to detect an interruption or an irregularity in the breathing pattern, for triggering a ventilator to initiate assisted breathing, and for interrupting the assisted breathing periodically to wean the patient off of the assisted breathing regime, thereby restoring the patient's  
30 ability to breath independently.

In those instances in which a patient requires mechanical ventilation due to respiratory failure, a wide variety of mechanical ventilators are available. Most



5 modern ventilators allow the clinician to select and use several modes of inhalation  
either individually or in combination via the ventilator setting controls that are  
common to the ventilators. These modes can be defined in three broad categories:  
spontaneous, assisted or controlled. During spontaneous ventilation without other  
10 modes of ventilation, the patient breathes at his own pace, but other interventions may  
affect other parameters of ventilation including the tidal volume and the baseline  
pressure, above ambient, within the system. In assisted ventilation, the patient  
initiates the inhalation by lowering the baseline pressure by varying degrees, and then  
the ventilator "assists" the patient by completing the breath by the application of  
positive pressure. During controlled ventilation, the patient is unable to breathe  
15 spontaneously or initiate a breath, and is therefore dependent on the ventilator for  
every breath. During spontaneous or assisted ventilation, the patient is required to  
"work" (to varying degrees) by using the respiratory muscles in order to breath.

20 The work of breathing (the work to initiate and sustain a breath) performed by  
a patient to inhale while intubated and attached to the ventilator may be divided into  
two major components: physiologic work of breathing (the work of breathing of the  
patient) and breathing apparatus imposed resistive work of breathing. The work of  
breathing can be measured and quantified in Joules/L of ventilation. In the past,  
techniques have been devised to supply ventilatory therapy to patients for the purpose  
25 of improving patient's efforts to breath by decreasing the work of breathing to sustain  
the breath. Still other techniques have been developed that aid in the reduction of the  
patient's inspiratory work required to trigger a ventilator system "ON" to assist the  
patient's breathing. It is desirable to reduce the effort expended by the patient in each  
of these phases, since a high work of breathing load can cause further damage to a  
30 weakened patient or be beyond the capacity or capability of small or disabled patients.  
It is further desirable to deliver the most appropriate mode, and, intra-mode, the most  
appropriate quality and quantity of ventilation support required the patient's current  
physiological needs.

5           The early generation of mechanical ventilators, prior to the mid-1960s, were  
designed to support alveolar ventilation and to provide supplemental oxygen for those  
patients who were unable to breathe due to neuromuscular impairment. Since that  
time, mechanical ventilators have become more sophisticated and complicated in  
10           response to increasing understanding of lung pathophysiology. Larger tidal volumes,  
an occasional "sigh breath," and a low level of positive end-expiratory pressure  
(PEEP) were introduced to overcome the gradual decrease in functional residual  
capacity (FRC) that occurs during positive-pressure ventilation (PPV) with lower tidal  
volumes and no PEEP. Because a decreased functional residual capacity is the  
15           primary pulmonary defect during acute lung injury, continuous positive pressure  
(CPAP) and PEEP became the primary modes of ventilatory support during acute  
lung injury.

          In an effort to improve a patient's tolerance of mechanical ventilation, assisted  
or patient-triggered ventilation modes were developed. Partial PPV support, in which  
20           mechanical support supplements spontaneous ventilation, became possible for adults  
outside the operating room when intermittent mandatory ventilation (IMV) became  
available in the 1970s. Varieties of "alternative" ventilation modes addressing the  
needs of severely impaired patients continue to be developed.

25           The second generation of ventilators was characterized by better electronics  
but, unfortunately, due to attempts to replace the continuous high gas flow IMV  
system with imperfect demand flow valves, failed to deliver high flow rates of gas in  
response to the patient's inspiratory effort. This apparent advance forced patient to  
perform excessive imposed work and thus, total work in order to overcome ventilator,  
30           circuit, and demand flow valve resistance and inertia. In recent years,  
microprocessors have been introduced into modern ventilators. Microprocessor  
ventilators are typically equipped with sensors that monitor breath-by-breath flow,  
pressure, volume, and derive mechanical respiratory parameters. Their ability to  
sense and transduce "accurately," combined with computer technology, makes the

5 interaction between clinician, patient, and ventilator more sophisticated than ever.  
The prior art microprocessor controlled ventilators suffered from compromised  
accuracy due to the placement of the sensors required to transduce the data signals.  
Consequently, complicated algorithms were developed so that the ventilators could  
"approximate" what was actually occurring within the patient's lungs on a breath by  
10 breath basis. In effect, the computer controlled prior art ventilators were limited to  
the precise, and unyielding, nature of the mathematical algorithms which attempted to  
mimic cause and effect in the ventilator support provided to the patient.

15 Unfortunately, as ventilators become more complicated and offer more  
options, the number of potentially dangerous clinical decisions increases. The  
physicians, nurses, and respiratory therapists that care for the critically ill are faced  
with expensive, complicated machines with few clear guidelines for their effective  
use. The setting, monitoring, and interpretation of some ventilatory parameters have  
become more speculative and empirical, leading to potentially hazardous misuse of  
20 these new ventilator modalities. For example, the physician taking care of the patient  
may decide to increase the pressure support ventilation (PSV) level based on the  
displayed spontaneous breathing frequency. This may result in an increase in the  
work of breathing of the patient which may not be appropriate. This "parameter-  
monitor" approach, unfortunately, threatens the patient with the provision of  
25 inappropriate levels of pressure support.

Ideally, ventilatory support should be tailored to each patient's existing  
pathophysiology, rather than employing a single technique for all patients with  
ventilatory failure (*i.e.*, in the example above, of the fallacy of using spontaneous  
30 breathing frequency to accurately infer a patient's work of breathing). Thus, current  
ventilatory support ranges from controlled mechanical ventilation to total spontaneous  
ventilation with CPAP for support of oxygenation and the elastic work of breathing  
and restoration of lung volume. Partial ventilation support bridges the gap for patients  
who are able to provide some ventilation effort but who cannot entirely support their

5 own alveolar ventilation. The decision-making process regarding the quality and quantity of ventilatory support is further complicated by the increasing knowledge of the effect of mechanical ventilation on other organ systems.

10 The overall performance of the assisted ventilatory system is determined by both physiological and mechanical factors. The physiological determinants, which include the nature of the pulmonary disease, the ventilatory efforts of the patient, and many other physiological variables, changes with time and are difficult to diagnosis. Moreover, the physician historically had relatively little control over these determinants. Mechanical input to the system, on the other hand, is to a large extent  
15 controlled and can be reasonably well characterized by examining the parameters of ventilator flow, volume, and/or pressure. Optimal ventilatory assistance requires both appropriately minimizing physiologic workloads to a tolerable level and decreasing imposed resistive workloads to zero. Doing both should insure that the patient is neither overstressed nor oversupported. Insufficient ventilatory support places  
20 unnecessary demands upon the patient's already compromised respiratory system, thereby inducing or increasing respiratory muscle fatigue. Excessive ventilatory support places the patient at risk for pulmonary-barotrauma, respiratory muscle deconditioning, and other complications of mechanical ventilation.

25 Unfortunately, none of the techniques devised to supply ventilatory support for the purpose of improving patient efforts to breath, by automatically decreasing imposed work of breathing to zero and appropriately decreasing physiologic work once a ventilator system has been triggered by a patient's inspiratory effort, provides the clinician with advice in the increasingly complicated decision-making process  
30 regarding the quality and quantity of ventilatory support. As noted above, it is desirable to reduce the effort expended by the patient to avoid unnecessary medical complications of the required respiratory support and to deliver the most appropriate mode, and, intra-mode, the most appropriate quality and quantity of ventilation support required the patient's current physiological needs. Even using the advanced

5 microprocessor controlled modern ventilators, the prior art apparatus and methods  
tend to depend upon mathematical models for determination of necessary actions. For  
example, a ventilator may sense that the hemoglobin oxygen saturation level of the  
patient is inappropriately low and, from the sensed data and based upon a determined  
10 mathematical relationship, the ventilator may determine that the oxygen content of the  
breathing gas supplied to the patient should be increased. This is similar to, and  
unfortunately as inaccurate as, a physician simply looking at a patient turning "blue"  
and determining more oxygen is needed.

15 From the above, in the complicated decision-making environment engendered  
by the modern ventilator, it is clear that it would be desirable to have a medical  
ventilator monitor system that alerts the clinician of the ventilator's failure to supply  
the appropriate quality and quantity of ventilatory support and provides advice to the  
clinician regarding the appropriate quality and quantity of ventilatory support that is  
tailored to the patient's pathophysiology. Such a ventilatory monitor system is  
20 unavailable in current systems.

#### SUMMARY

25 In accordance with the purposes of this invention, as embodied and broadly  
described herein, this invention, in one aspect, relates to a method of monitoring the  
ventilation support provided by a ventilator that is supplying a breathing gas to a  
patient via a breathing circuit that is in fluid communication with the lungs of the  
patient. The ventilator has a plurality of selectable ventilator setting controls  
30 governing the supply of ventilation support from the ventilator, each setting control  
selectable to a level setting. The ventilator support monitor system preferably  
receives at least one ventilator setting parameter signal, each ventilator setting  
parameter signal indicative of the level settings of one ventilator setting control,  
monitors a plurality of sensors, each sensor producing an output signal indicative of a

5 measured ventilation support parameter, to determine the sufficiency of the ventilation  
support received by the patient, and determines the desired level settings of the  
ventilator setting controls in response to the received ventilator setting parameter  
signal and the output signals. The ventilator support monitor system preferably  
utilizes a trainable neural network to determine the desired level settings of the  
10 ventilator setting controls.

In another aspect, the invention relates to a ventilator support monitor system  
that supplies a breathing gas to a patient via a breathing circuit in fluid  
communication with the ventilator and the lungs of a patient. The ventilator  
15 preferably has at least one selectable ventilator setting control. The selectable  
ventilator setting control governs the supply of ventilation support from the ventilator  
to the patient via the breathing circuit. Each ventilator setting control generates a  
ventilator setting parameter signal indicative of the current level setting of the  
ventilator setting.

20 The ventilator support monitor system has a plurality of sensors and a  
processing subsystem. The sensors measure a plurality of ventilation support  
parameters and each sensor generates an output signal based on the measured  
ventilation support parameter. The processing subsystem is connected to receive the  
25 output signal from the sensor and the ventilator setting signal(s) from the ventilator  
setting control(s). The processor of the processing subsystem runs under control of a  
program stored in the memory of the processing subsystem and determines a desired  
level setting of at least one ventilator setting control in response to the ventilator  
setting parameter signal and the output signal. The processing subsystem of the  
30 ventilator preferably utilizes a trainable neural network to determine the desired level  
settings of the ventilator setting controls.

5 DETAILED DESCRIPTION OF THE FIGURES

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principals of the invention.

10 Fig. 1 is a block diagram of one configuration a ventilator monitor system for determining the desired ventilator control settings of a ventilator.

15 Fig. 2A is a block diagram of one configuration of the ventilator monitor system showing the ventilator providing ventilation support to a patient connected to the ventilator via a breathing circuit.

20 Fig. 2B is a block diagram of an embodiment of a ventilator monitor system showing the monitor system incorporated into the ventilator.

25 Fig. 3 is a block diagram of the ventilator monitor system showing a plurality of sensors connected to the processing subsystem.

Fig. 4 is a block diagram of a processing subsystem of the present invention.

30 Fig. 5 is a block diagram of a feature extraction subsystem of the present invention.

Fig. 6A is a block diagram of one embodiment of the intelligence subsystem of the processing subsystem.

Fig. 6B is a block diagram of a second embodiment of the intelligence subsystem of the processing subsystem.

5            Fig. 7 is a schematic block diagram of one realization of the system of the invention.

            Fig. 8 is a diagram of the basic structure of an artificial neural network having a layered structure.

10  
  
                                 DETAILED DESCRIPTION OF THE INVENTION

            The present invention is more particularly described in the following examples  
15            that are intended to be illustrative only since numerous modifications and variations therein will be apparent to those skilled in the art. As used in the specification and in the claims, the singular form "a," "an" and "the" include plural referents unless the context clearly dictates otherwise.

20            As depicted in Figs. 1 - 3, the ventilator monitor system 10 of the present invention preferably comprises a conventional ventilator 20, a processing subsystem 40, a measuring system, and a display 62. The ventilator 20 supplies a breathing gas to the lungs of the patient P via a breathing circuit 22 that typically comprises an  
                                 inspiratory line 23, an expiratory line 24, and a patient connection tube 25, all  
25            connected by a patient connector 26. The preferred ventilator 20 is a microprocessor-controlled ventilator of a type that is exemplified by a Mallinckrodt, Nelcor, Puritan-Bennet, 7200ae, or a Bird 6400 Ventilator.

            To control the delivery of the breathing gas, the preferred ventilator 20  
30            typically has at least one selectable ventilator setting control 30 operatively connected to the processing system 40 for governing the supply of ventilation support provided to the patient P. As one skilled in the art will appreciate, each ventilator setting control 30 is selectable to a desired level setting. Such a ventilator 20 is particularly



5 useful in controlling the delivery of breathing support so that the quantity and quality  
of ventilation support coincides with the physiological support needs of the patient P.

10 In the preferred embodiment, the preferred ventilator 20 can operate  
selectively in one or more conventional modes, as needed and selected by the operator  
and/or the processing subsystem 40, including but not limited to: (i) assist control  
ventilation (ACMV); (ii) synchronized intermittent mandatory ventilation (SIMV); (iii)  
continuous positive airway pressure (CPAP); (iv) pressure-control ventilation (PCV);  
15 (v) pressure support ventilation (PSV); (vi) proportional assist ventilation (PAV); and  
(vii) volume assured pressure support (VAPS). Further, the level setting of one or  
more conventional ventilator setting controls 30 of the ventilator 20 (*i.e.*, the intra-  
mode setting controls of the ventilator 20) may be adjusted, as needed and selected by  
the operator and/or the processing system 40 in order to maintain the sufficiency of  
ventilation support delivered to the patient P. The ventilator setting controls 30 of the  
ventilator 20 include but are not limited to controls for setting: (i) a minute ventilation  
20 ( $V_e$ ) level; (ii) a ventilator breathing frequency ( $f$ ) level; (iii) a tidal volume ( $V_T$ )  
level; (iv) a breathing gas flow rate ( $V$ ) level; (v) a pressure limit level; (vi) a work of  
breathing (WOB) level; (vii) a pressure support ventilation (PSV) level; (viii) a  
positive end expiratory pressure (PEEP) level; (ix) a continuous positive airway  
pressure (CPAP) level; and (x) a fractional inhaled oxygen concentration ( $FIO_2$ )  
25 level.

30 The conventional ventilator 20 contemplated typically has a gas delivery  
system and may also have a gas composition control system. The gas delivery system  
may, for example, be a pneumatic subsystem 32 in fluid/flow communication with a  
gas source 34 of one or more breathing gases and the breathing circuit 22 and in  
operative connection with the ventilator control settings 30 of the ventilator 20 and  
the processing subsystem 40. The breathing circuit 22 is in fluid communication with  
the lungs of the patient P. As one skilled in the art will appreciate, the pneumatic  
subsystem 40 of the ventilator 20 and the operative connection of that pneumatic

5 subsystem 40 to the source of breathing gas 34 of the ventilator 20 may be any design known in the art that has at least one actuator (not shown) that is capable of being operatively coupled, preferably electrically coupled, to the ventilator setting controls 30 for control of, for example, the flow rate, frequency, and/or pressure of the breathing gas delivered by the ventilator 20 to the patient P from the gas source 34.  
10 Such a pneumatic system 32 is disclosed in U.S. Patents Nos. 4,838,259 to Gluck *et al.*, 5,303,698 to Tobia *et al.*, 5,400,777 to Olsson *et al.*, 5,429,123 to Shaffer *et al.*, and 5,692,497 to Schnitzer *et al.*, all of which are incorporated in their entirety by reference herein and is exemplified by the Mallinckrodt, Nelcor, Puritan-Bennet, 7200ae, and the Bird 6400 Ventilator.

15 The gas composition control system may, for example, be an oxygen control subsystem 36 coupled to the source of breathing gas 34 and in operative connection to the ventilator setting controls 30 of the ventilator 20 and the processing subsystem 40. The oxygen control subsystem 36 allows for the preferred control of the percentage composition of the gases supplied to the patient P. As one skilled in the art will appreciate, the oxygen control subsystem 36 of the ventilator 20 and the operative connection of that oxygen control subsystem 36 to the pneumatic subsystem 32 and to the source of breathing gas 34 of the ventilator 20 may be any design known in the art that has at least one actuator (not shown) that is capable of being operatively coupled,  
20 preferably electrically coupled, to the ventilator setting controls 30 for control of, for example, the percentage composition of the oxygen supplied to the patient P.  
25

30 The processing subsystem 40 of the ventilator monitor system 10 preferably has an input 44 that is operatively coupled to the ventilator setting controls 30 of the ventilator 20 so that at least one ventilator setting parameter signal 42 may be received by the processing subsystem 40. Each ventilator setting parameter signal 42 is preferably indicative of a setting of a ventilator setting control 30. Thus, the processing system 40 is in receipt of signals 42, preferably continuously, indicative of the current level settings of the ventilator setting controls 30. As one skilled in the art

5 will appreciate, the current level settings of the ventilator setting controls 30 may be stored in the memory of the processing subsystem 40. In this example, the ventilator setting parameter signals 42 would be input from the memory of the processing subsystem 40 to the processor for continued processing and assessment.

10 For example, the input of the processing system 40 may receive one or more of the following ventilator setting parameter signals 42: a minute ventilation ( $V_E$ ) signal indicative of the  $V_E$  level set on the ventilator 20; a ventilator breathing frequency ( $f$ ) signal indicative of the  $f$  level set on the ventilator 20; a tidal volume ( $V_T$ ) signal indicative of the  $V_T$  level set on the ventilator 20; a breathing gas flow rate (V) signal indicative of the V level set on the ventilator 20; a pressure limit signal indicative of the pressure limit set on the ventilator 20; a work of breathing (WOB) signal indicative of the WOB level set on the ventilator 20; a pressure support ventilation (PSV) signal indicative of the PSV level set on the ventilator 20; a positive end expiratory pressure (PEEP) signal indicative of the PEEP level set on the ventilator 20; a continuous positive airway pressure (CPAP) signal indicative of the CPAP level set on the ventilator 20; and a fractional inhaled oxygen concentration (FIO2) signal indicative of the FIO2 level set on the ventilator 20.

25 The measuring system of the monitor system 10 is also operatively connected to the processing subsystem 40. The measuring system senses and measures a plurality of ventilation support parameters which are indicative of the ventilation support provided to the patient P and the physiological condition of the patient P. It is contemplated that the measuring system may comprise at least one sensor 52, and preferably comprises a plurality of sensors 52, for capturing the desired ventilation support data. Each sensor 52 generates an output signal 51 based on the particular measured ventilation support parameter.

30 In one preferred embodiment shown in Fig. 3, the processing subsystem 30 is shown operatively connected to a flow rate sensor 53, a exhaled CO2 (Ex CO2) ✓

*a plurality of sensors such as*

5 sensor 54, a pressure sensor 55, a blood pressure sensor 56, and a SPO2 sensor 57. In  
this embodiment, it is preferred that the monitor system 10 be responsive to the output  
signals 51 input into the processing subsystem 40 from, for example: i) the flow rate  
10 sensor 53 which is indicative of the flow rate ventilation support parameter of the gas  
expired/inspired by the patient P within the breathing circuit 22, ii) the gas pressure  
sensor 55 which is indicative of the pressure ventilation support parameter of the  
breathing gas within the breathing circuit 22, and iii) the Ex CO2 sensor 54 which is  
indicative of the exhaled carbon dioxide ventilation support parameter present in the  
exhaled gas expired by the patient P within the breathing circuit 22 (i.e., the flow rate  
15 output signal 51 generated by the flow rate sensor 53, the gas pressure output signal  
51 generated by the gas pressure sensor 55, and the Ex CO2 output signal 51  
generated by the Ex CO2 sensor 54). Optionally, the monitor system 10 may be  
responsive to output signals 51 input into the processing subsystem 40 from the  
output of the blood pressure sensor 56, which is indicative of the blood pressure  
20 ventilation support parameter of the patient P, for example the arterial systolic,  
diastolic, and mean blood pressure of the patient P, and the SPO2 sensor 57 which is  
indicative of the hemoglobin oxygen saturation level ventilation support parameter of  
the patient P (i.e., the blood pressure output signal 51 generated by the blood pressure  
sensor 56 and the SPO2 output signal 51 generated by the SPO2 sensor 57).

25 The flow rate sensor 53, the pressure sensor 55, and the Ex CO2 sensor 54 are  
preferably positioned between the patient connector 26 and the patient connection  
tube 25. Alternatively, it is preferred that the pressure sensor 55 be located at the  
tracheal end of the patient connection tube 25. The flow rate, pressure, and Ex CO2  
30 sensors 53, 55, 54 are exemplified by Novametrics, CO<sub>2</sub>SMO+ monitor (which has a  
flow rate, pressure and Ex CO2 sensors). The blood pressure sensor 56 and the SPO2  
sensor 57 are exemplified by Dynamap, Inc.'s blood pressure sensor and  
Novametrics, CO<sub>2</sub>SMO+ monitor's SPO2 sensor. The blood pressure sensor 56 and  
the SPO2 sensor 57 may be attached to a portion of the patient's body to render the  
requisite measurements. For example, the blood pressure sensor 56, here for example

5 shown as a blood pressure cuff, is shown attached to the arm of the patient P and the  
SPO2 sensor 57, which may, for example, be a pulse oximeter, is shown attached to a  
10 finger of the patient 12. One skilled in the art will appreciate, the blood pressure data  
may be derived from the SPO2 sensor 57 which eliminates the need for the blood  
pressure sensor 56.

10 Additional standard equipment can include an operator interface 60, which in  
the preferred embodiment is a membrane keypad, a keyboard, a mouse, or other  
suitable input device, for providing user inputs of both data and control commands  
needed to execute the software which implements the various functions of the  
15 invention. The operator of the ventilator monitor system 10 of the present invention  
may provide the processing subsystem 40, via an operator input signal generated by  
the operator interface 60, with any number of applicable input parameters, such as  
patient identification information, patient age, patient weight, or other desired patient  
statistics. It is preferred that the operator input predetermined patient reference data,  
20 such as the arterial blood gas ph, the arterial blood gas PaO2, and/or the arterial blood  
gas PaCO2 of the patient's blood, and/or patient's temperature into the processing  
subsystem 40 as operator input signals 61 via the operator interface 60. The monitor  
system 10 may also be responsive to the core body temperature of the patient P which  
may be input into the processing subsystem 40 as an output signal 51 from a  
25 temperature sensor 58 attached to the patient P or as an operator input signal 61 via  
the operator interface 60.

30 The processing subsystem 40 preferably comprises a processor 46, for  
example a microprocessor, a hybrid hardware/software system, controller, or  
computer, and a memory. The output signals 51 and the ventilation data 72 derived  
from the output signals 51 are stored in the memory of the processing subsystem 40 at  
user-defined rates, which may be continuous, for as-needed retrieval and analysis.  
The ventilator setting signal 42 may also be stored in the memory at a user-defined  
rate. As one skilled with the art will appreciate, any generated signal may be stored in

5 the memory at user-defined rates. The memory may be, for example, a floppy disk drive, a CD drive, internal RAM or hard drive of the associated processor 12.

10 The processing subsystem 40 is responsive to the output signals 51 of the measuring means, the ventilator setting parameter signal(s) 42, and, if provided, the operator input signals 61. The processor 46 runs under the control of a program stored in the memory and has intelligent programming for the determination of at least one desired level setting of the ventilator setting controls 30 based on at least a portion of the output signal 51 from the measuring means, at least a portion of the ventilator setting parameter signal(s) 42 received at the input 44 of the processing  
15 subsystem 40, and, if provided, at least a portion of the operator input signals 61.

20 The desired level settings for the ventilator setting controls 30 of the ventilator 20 may include at least one of the group of: i) a minute ventilation ( $V_E$ ) level indicative of the desired  $V_E$  level to set on the ventilator 20; ii) a ventilator breathing frequency ( $f$ ) level indicative of the desired  $f$  level to set on the ventilator 20; iii) a tidal volume ( $V_T$ ) level indicative of the  $V_T$  level to set on the ventilator 20; iv) a breathing gas flow rate ( $V$ ) level indicative of the  $V$  level to set on the ventilator 20; v) a pressure limit level indicative of the pressure limit level to set on the ventilator 20; vi) a work of breathing (WOB) level indicative of the WOB level to set on the ventilator 20; vii) a pressure support ventilation (PSV) level indicative of the PSV level to set on the ventilator 20; viii) a positive end expiratory pressure (PEEP) level indicative of the PEEP level to set on the ventilator 20; ix) a continuous positive airway pressure (CPAP) level indicative of the CPAP level to set on the ventilator 20; and x) a fractional inhaled oxygen concentration ( $FIO_2$ ) level indicative of the  $FIO_2$   
25 level to set on the ventilator 20.  
30

The desired level setting of the ventilator setting controls 30 determined by the processing system 40 of the monitor system 10 may be displayed to the operator via the display. The display of the monitor system 10 preferably comprises a visual

5 display 62 or CRT, electronically coupled to the processing subsystem 40 for  
outputting and displaying output display signals generated from the processing  
subsystem 40.

10 Still further, the monitor system 10 may have an alarm 21 for alerting the  
operator of either a failure of the monitor system 10, such as a power failure or loss of  
signal data input, or an inappropriate setting of a ventilator control 30, such as a level  
setting of a ventilator setting control 30 currently controlling the delivery of ventilator  
support to the patient P differing from a recommended desired level setting of the  
15 ventilator setting control 30. Preferably, the alarm 21 comprises a visual and/or audio  
alarm, but any means for alerting the operating clinician know to one skilled in the art  
may be used. Of course, it is desired to use a backup power supply, such as a battery.

Referring to Figs. 4 and 5, the processing subsystem of the preferred  
embodiment of the present invention has a means for determining the desired  
20 ventilation control settings 30 of the ventilator 20. The determining means preferably  
comprises a feature extraction subsystem 70 and an intelligence subsystem 80. The  
feature extraction subsystem 70 has a means for extracting and compiling pertinent  
ventilation data features from the input of the measuring means (*i.e.*, the output  
signals 51). In effect, the feature extraction subsystem 70 acts as a preprocessor for  
25 the intelligence subsystem 80. An example of the feature extraction subsystem 70 is  
shown in Fig. 5. Here, a flow rate sensor 53, a gas pressure sensor 55, a SPO2 sensor  
57, an Ex CO2 sensor 54, a temperature (T) sensor 58, a blood pressure (BP) sensor  
56, of a type described above, and any other desired sensor are operatively connected  
to the feature extraction subsystem 70 of the processing subsystem 40. Preferably, the  
30 flow rate sensor 53, the gas pressure sensor 55, and the Ex CO2 sensor 54 provide the  
only inputs to the monitor system. The other sensor inputs, and the user input, may be  
included to increase the reliability and confidence of the determined desired level  
settings of the controls 30. The monitor system 10 preferably adjusts the extraction of  
ventilator data 72 as a function of the presence or absence of these optional inputs.

5 By making the number of inputs optional, which also makes the required number of  
sensors 52 comprising the measuring system optional, the number of environments in  
which the ventilator monitor system 10 can be used is increased.

10 The purpose of the feature extraction subsystem 70 is to calculate and/or  
identify and extract important variables or features from the output signals 51  
produced by the measuring means. For example, from the exemplified required  
inputs to the feature extraction subsystem 70, i.e., the gas pressure output signal 51,  
the flow rate output signal 51, and the Ex CO<sub>2</sub> output signal 51, a plurality of  
ventilation data 72 may be derived. The derived ventilation data 72 may comprise:  
15 the values of any output signals 51 used, such as, for example, the gas pressure output  
signal 51, the flow rate output signal 51, and the Ex CO<sub>2</sub> output signal 51 output  
signals 51; the peak inflation pressure (PIP), which is the maximal pressure generated  
during mechanical ventilation of the lungs; the mean airway pressure (PAW), which is  
the average positive pressure measured at the airway opening in the patient  
20 connection tube 25 or in the breathing circuit 22 over one minute; the positive end  
expiratory pressure (PEEP), which is the baseline or starting positive pressure prior to  
mechanical inflation or the positive pressure applied continuously during inhalation  
and exhalation during spontaneous ventilation; breathing frequency (f), which is the  
frequency or rate or breathing per minute (the total breathing frequency  $f_{TOT}$  is the  
25 sum of the mechanical  $f_{MECH}$  ventilator preselected frequency and the spontaneous  
 $f_{SPON}$  patient breathing frequency); the tidal volume ( $V_T$ ), which is the volume of the  
breathing gas moving in and out of the lungs per breath ( $V_{T MECH}$  is the ventilator  
preselected  $V_T$  per breath and  $V_{T SPON}$  is the inhaled and exhaled volume per breath of  
the patient); the minute exhaled ventilation ( $V_E$ ), which is the volume of breathing  
30 gas moving in and out of the lungs of the patient per minute ( $V_E$  is the product of the  
breathing frequency f and the tidal volume ( $V_E = f \times V_T$ ), and the  $V_{E TOT}$  is the sum of  
the ventilator preselected  $V_E$  ( $V_{E MECH}$ ) and the spontaneous patient  $V_E$  inhaled and  
exhaled per minute ( $V_{E SPON}$ )); the inhalation-to-exhalation time ratio (I:E ratio),  
which is the ratio of inhalation time to exhalation time during mechanical ventilation;

*The gas pressure*



5 the physiologic dead space volume ( $V_{Dphys}$ ), which is the volume of gas in the  
anatomic airway and in ventilated, unperfused alveoli that does not participate in  
blood gas exchange; the lung carbon dioxide elimination rate ( $LCO_2$ ), which is the  
volume of  $CO_2$  exhaled per breath or per minute ( $LCO_2$  is the area under the Ex  $CO_2$   
and volume curve); the partial pressure end-tidal carbon dioxide level ( $PetCO_2$ ),  
10 which is the partial pressure of the exhaled  $CO_2$  measured at the end of the  
exhalation; the cardiac output (CO) of the patient, which is the amount of blood  
ejected from the heart per minute and which may, for example be derived from the  
determined  $LCO_2$  rate; the respiratory system compliance and resistance; the  
respiratory muscle pressure, the work of breathing of the patient which may be  
15 derived from the determined respiratory muscle pressure; and pressure-volume loops.

Ventilation data 72 may also be derived from the exemplified optional inputs  
to the feature extraction subsystem 70. From the  $SPO_2$  output signal 51, the arterial  
blood hemoglobin oxygen saturation level and the heart rate may be determined, and  
20 the pulsatile blood pressure waveform of the  $SPO_2$  output signal 51 may be used to  
determine arterial blood pressure. Additionally, from the blood pressure output signal  
51, the arterial systolic, diastolic and mean blood pressure of the patient P may be  
determined. Further, from the temperature output signal 51, the core body  
temperature of the patient may 12 be derived. Still further, from the arterial blood  
25 hemoglobin oxygen saturation level and the determined  $LCO_2$ , the dead space volume  
may be determined.

The feature extraction subsystem 70 may also receive user input via the  
operator interface 60 and may receive the ventilator setting parameter signal 42. The  
30 ventilation data 72 is preferably compiled in the feature extraction subsystem 70 and a  
feature vector 74 or matrix is preferably generated which contains all of the  
ventilation data items used by the monitor subsystem 10 to perform the ventilation  
support assessment process. The feature vector 74 may be updated at user-defined  
intervals such as, for example, after each breath or each minute and is output from the